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Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/683,789
Filing Date: October 10, 2003
Appellant(s): WILHELM ET AL.

MAILED
SEP 27 2005
GROUP 1600

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 05 July 2005 appealing from the Office action mailed 04 May 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

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(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

Appellant states at page 4 of the appeal brief filed 05 July 2005 that the negative claim limitation in claims 1, 10, 20 and 28 was the only avenue available for Appellants to seek meaningful patent protection based on the filing fees already paid. However, this was not the only avenue available. Appellant could have filed the Markush group as filed on 08 December 2004 and petitioned the restriction if such a restriction was required.

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1, 3-26 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims 1, 10, 20, and 28 provide a negative limitation, excluding a hydrogen ion or ion aggregate from the mammalian substance to be detected. It is noted that the original specification on page 2, lines 8-13 discloses a hydrogen ion or ion aggregate as a mammalian substance capable of being detected, but the original specification does not disclose the negative limitation of excluding a hydrogen ion or ion aggregate from detection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1, 3-11, 14-20, 22-26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diehl et al. (US 2003/015830) in view of Ponce et al. (Critical Revision of

Presumptive Tests for Bloodstains, Forensic Science Communications, Vol. 1, No. 2, July 1999) further in view of Rittersdorf et al. (US 3,917,452).

With respect to claims 1, 3-5, 10-11, 14-20, 22, 25-26 and 28, Diehl et al. teach a wearable article equipped with a multi-level alert system wherein three or more levels of a mammalian substance in a mammalian extract are detected, the article comprising: a substrate (par. 0034, lines 1-5); a target area on the substrate including first, second, and third sub-areas for receiving the mammalian extract (area where indicator is applied; par. 0034, lines 5-18); and a chemical detection system on the target area for detecting a first lower level of the mammalian substance, a second chemical composition in the second sub-area for detecting a second higher level of the mammalian substance, and a third chemical composition in the third sub-area for detecting a third level of the mammalian substance (Fig. 5; Fig. 6; par. 0028; par. 0029, lines 14-39), wherein the chemical detection system comprises a different chemical composition on the first, second, and third sub-areas (par. 0028; par. 0029, lines 14-26). Detection is performed by the chemical composition on the substrate, after which a signal (color change) is initiated and is emitted by each sub-area in response to a respective level of the mammalian substance (Fig. 5; Fig. 6; par. 0029, lines 22-29). The first and second signals can be compared to quantify the first level of the mammalian substance (par. 0029, lines 36-42). Diehl et al. fail to teach a mammalian substance not being a hydrogen ion or ion aggregate.

Ponce et al. teach semiporous filter paper with a first chemical composition comprising phenolphthalein, a second chemical composition comprising o-tolidine, and a third chemical composition comprising leucomalachite (Materials and Methods, reagents) in order to test for false results in blood detection using reagents that detect different levels of blood in a sample

(Evaluation of the Results, paragraph 3), but fails to provide motivation to include the chemical compositions in the wearable article of Diehl et al.

However, Rittersdorf et al. teach that the detection of blood in urine, feces, and vomit allows for diagnosis of hemorrhages in the urinary tract (col. 1, lines 8-13 and 30-34).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute for the reagents of Diehl et al., or further include in the form of a separate indicator in the wearable article as taught by Diehl et al., the compositions to detect blood as taught by Ponce et al., in order to provide a multi-level alert system capable of detecting small amounts of blood in urine to diagnose hemorrhages as taught by Rittersdorf et al.

Regarding claims 6-9, Diehl et al. teach the wearable article being a personal care absorbent article (diaper, par. 0015, lines 20-24), a medical absorbent article (bandage, par. 0015, lines 20-24), an athletic absorbent article (underwear, par. 0015, lines 20-24), a nonabsorbent article (belt, par. 0014, lines 4-11), a garment (underwear, par. 0015, lines 20-24), or an article of clothing (underwear, par. 0014, lines 4-11).

With respect to claims 23 and 24, Diehl et al. teach the wearable article wherein the first, second, and third sub-areas comprise strips, adjacent shapes, numbers, symbols, letters, or words (par. 0028, lines 8-11).

3. Claims 10, 12, 13, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Springer et al. (US 6,617,488) in view of Ponce et al. (Critical Revision of Presumptive Tests for Bloodstains, Forensic Science Communications, Vol. 1, No. 2, July 1999) further in view of Rittersdorf et al. (US 3,917,452).

Regarding claims 10, 20 and 21, Springer et al. teach a wearable article equipped with a multi-level alert system for detecting, and initiating and emitting a signal in response to three or more levels of a mammalian substance in a mammalian extract, the wearable article comprising: a substrate (col. 8, lines 15-23), a target area on the substrate comprising first, second, and third sub-areas (col. 7, lines 13-20 and 36-39) in the form of concentric shapes (bullseye, col. 10, lines 39-40), and a chemical detection system on the target area which detects and initiates a first, second, and third signal, in response to a respective first, second, and third level of mammalian substance (col. 7, lines 13-20 and 28-35). Springer et al. also teach the chemical compositions in the sub-areas adapted to detect different levels of mammalian substance in the mammalian extract (col. 7, lines 13-26). However, Springer et al. fail to teach the mammalian substance excluding a hydrogen ion and an ion aggregate.

Ponce et al. teach semiporous filter paper with a first chemical composition comprising phenolphthalein, a second chemical composition comprising o-tolidine, and a third chemical composition comprising leucomalachite (Materials and Methods, reagents) in order to test for false results in blood detection using reagents that detect different levels of blood in a sample (Evaluation of the Results, paragraph 3), but fails to provide motivation to include the chemical compositions in the wearable article of Springer et al.

However, Rittersdorf et al. teach that the detection of blood in urine, feces, and vomit allows for diagnosis of hemorrhages in the stomach, intestines, and urinary tract (col. 1, lines 8-13 and 30-34).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the wearable article as taught by Springer et al., the compositions to detect blood as taught by Ponce et al., in order to provide a multi-level alert system capable of detecting small amounts of blood to diagnose hemorrhages as taught by Rittersdorf et al.

With respect to claims 12 and 13, Springer et al. teach a wearable article wherein the first and second signal comprise a respective light or a respective sound in response to a level of mammalian substance (col. 10, lines 13-20). Spring et al. teach an electrochemical indicator, including a mammalian substance sensor, comprising the compositions of the first, second, and third sub-area and an electrochemical cell (col. 8, lines 44-52). The mammalian substance sensor provides an electrical signal, such as an electric potential that depends on the level of mammalian substance, and emits a visual indication (light) or an audible signal (sound).

(10) Response to Argument

A. Rejection of Claims 1, 3-26 and 28 under 35 USC §112, first paragraph.

At pages 4-5, appellant summarizes examiner's position regarding the rejection of claims 1, 3-26 and 28 under 35 USC 112, first paragraph.

At pages 6-7, appellant argues that according to In re Johnson, hydrogen ions and ion aggregates may be explicitly excluded from the claims because the specification has described the "whole" inventive concept and because hydrogen ions and ion aggregates are positively recited in the original specification. However, the genus of mammalian substances has not been sufficiently described in the original specification. Merely teaching at page 2, lines 8-10 that a mammalian substance is any substance not normally found in a particular mammalian extract or abnormal levels of any substance typically found in a mammalian extract at normal levels is not sufficient to define the genus of a mammalian substance. Appellant does not define a "normal level" or what encompasses a substance "not normally found" in a particular extract, therefore a mammalian substance is not sufficiently defined. Furthermore, if a particular species (ie. hydrogen ions and ion aggregates) is to be excluded from the claims, the limitation must be found in the original specification according to 35 USC 112, first paragraph. The original specification teaches hydrogen ions and ion aggregates as a mammalian substance, but do not specifically teach excluding a hydrogen ion or ion aggregate from the genus of a mammalian substance.

At page 7, appellant argues that according to Ex Parte Parks, negative claim limitations are supported by the specification even where the negative limitations were not directed to a species, and there was no genus. Appellant argues that according to the specification, appellant had possession of embodiments of the claimed invention wherein the mammalian substance being detected is not a hydrogen ion or ion aggregate. While the original specification provides support for a mammalian substance being one of 14 substances recited as a Markush group at page 2 of the specification, the original specification does not support a genus of mammalian substances excluding hydrogen ions and ion aggregates. The original specification must specifically exclude a hydrogen ion or ion aggregate from a mammalian substance or sufficiently define the genus of a mammalian substance in order to provide sufficient support.

B and C. Rejection of Claims 1, 3-26 and 28 under 35 USC §103(a).

At pages 8-9, appellant summarizes examiner's position regarding the rejection of claims 1, 3-11, 14-20, 22-26 and 28 under 35 USC 103(a).

At page 12, appellant summarizes examiner's position regarding the rejection of claims 10, 12, 13, 20 and 21 under 35 USC 103(a).

Appellant provides similar arguments for the rejections under 35 USC 103(a) over Diehl et al. in view of Ponce et al. further in view of Rittersdorf et al. (pages 8-12) and under 35 USC 103(a) over Springer et al. in view of Ponce et al. further in view of Rittersdorf et al. (pages 12-14). Response to appellant's arguments are combined below.

At pages 9 and 12, appellant argues that no explanation as to how or where Rittersdorf et al. provides motivation to combine Ponce et al. with Diehl et al. or Springer et al. However, as described above, Rittersdorf et al. teach that the detection of blood in urine allows for diagnosis of hemorrhages in the stomach, intestines, and urinary tract at column 1, lines 8-13 and 30-34. Therefore one of ordinary skill would recognize that the reagents of Ponce et al., which detect blood, could be substituted in Diehl et al. or Springer et al. in order to detect blood instead of pH as motivated by Rittersdorf et al.

At pages 9-10 and 13, appellant argues that no explanation is provided as to how the reagents in Ponce et al. can be successfully employed in the dehydration indicator of Diehl et al. or Springer et al., or how the reagents of Ponce et al. are employed to measure ionic strength or indicate dehydration as required by Diehl et al./Springer et al. Appellant further argues that it is not clear whether the chemical reagents of Ponce et al. are substituted for the chemical compositions in Diehl et al./Springer et al. or added to the chemical reagents of Ponce et al. However, as described in section (9), one of ordinary skill in the art would recognize that the reagents of Ponce et al. are not employed to measure ionic strength and are instead substituted for the reagents in the device of Diehl et al./Springer et al. to detect blood in urine as motivated by Rittersdorf et al. One of ordinary skill in the art would also recognize that the reagents of

Ponce et al. could be incorporated in a separate indicator in addition to the pH indicator of Diehl et al./Springer et al. so the article detects both pH and blood in urine.

At pages 10 and 13, appellant argues that if the oxidation-reduction compositions of Ponce et al. were added to the chemical compositions of Diehl et al./Springer et al., the dehydration indicator would not provide an accurate measurement of the ionic strength or level of dehydration in a wearer's urine. However, such a combination is not what one of ordinary skill in the art would find obvious. As described above in section (9), it would have been obvious to substitute the chemical reagents of Ponce et al. for the chemical reagents of Diehl et al./Springer et al. in order to detect blood in urine instead of pH of urine.

At pages 10 and 13-14, appellant argues that the inclusion of oxidation-reduction reagents of Ponce et al. would completely change the principle of operation of the dehydration indicator of Diehl et al. However, changing the dehydration indicator of Diehl et al./Springer et al. to detect blood in urine instead of dehydration, is motivated by Rittersdorf et al., as described in section (9) above.

At page 11, appellant argues that a buffer agent is required to control the pH to prevent false results in Rittersdorf et al., and that if such a buffer agent were added to urine to control pH then it would no longer be possible to measure the dehydration of urine by measuring its ionic strength as disclosed in Diehl et al. Appellant argues that Rittersdorf et al. thus teaches away from adding the reagents of Ponce et al. to the dehydration indicator of Diehl et al. However, Rittersdorf et al. is not relied upon for reagents or methods of measuring mammalian substances. Rittersdorf et al. is relied upon only to provide motivation to include the reagents of Ponce et al. in the device of Diehl et al. to measure the amount of blood in urine. One of ordinary skill in the art would recognize that although the method of Rittersdorf et al. requires buffers, the reagents of Ponce et al., not Rittersdorf et al., are included in the device of Diehl et al. Therefore, the buffers of Rittersdorf et al. are not required and would not be included in the device of Diehl et al. Furthermore even if buffers were required and present in the device, the device of Diehl et al. in view of Ponce et al. further in view of Rittersdorf et al. measures the amount of blood in urine, not pH, so the presence of any buffers would not interfere with detection of blood.

At pages 11 and 14, appellant argues that the pH indicators of Diehl et al. and Springer et al. would still be able to detect hydrogen ions and/or ion aggregates if the reagents of Ponce et al. did not render the indicator of Diehl et al. or Springer et al. inoperable. However, one of ordinary skill in the art would recognize that the reagents of Ponce et al. would be substituted for the reagents of Diehl et al. or Springer et al. in order to detect blood in urine, instead of pH, as motivated by Rittersdorf et al. Therefore, detection of hydrogen ions or ion aggregates are excluded and blood is detected.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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James C. Housel